

of busulfan pharmacokinetics. In conjunction with sparse sampling, the proposed model-based dosing algorithm appears to ensure that patients achieve and maintain the expected target exposure.

**Conclusion:** In contrast to the current clinical protocol, which relies on a linear correlation between dose and body weight, our findings reveal the clinical implications of a nonlinear correlation between body size, liver function, and drug elimination. The definition of the sparse ideal optimal design for busulfan constitutes an important improvement in therapeutic drug monitoring routine. Moreover, the availability of a model-based dosing algorithm for dose individualization may contribute to considerable improvement in the safety and efficacy profile of patients undergoing treatment for stem cell transplantation.

**Disclosure of Interest:** None declared.

## OC021—CLINICAL TRIALS REGISTRY AND GOOD CLINICAL PRACTICE: IN INDIAN SCENARIO

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**Introduction:** In present scenario, India becomes a hub for conducting clinical trials. Hence, need good clinical practice (GCP) to conduct a clinical trial. Initiative of Indian government of clinical trial registry (CTRI) has helped in increasing transparency, accountability, and accessibility of clinical trials. We conducted retrospective observational study aimed to establish current Indian status of Good Clinical Practice certified clinical investigators in major government hospitals, private hospitals, and small polyclinic.

**Patients (or Materials) and Methods:** We have done extensive search of clinical trials registry in India to obtain information regarding the total number of trials registered and further divided into the sites specific like major government hospitals, private hospitals, and small polyclinic from year 2007 to 2012.

**Results:** Our paper is first of a kind to demonstrate the sites preferred by sponsor or investigator for conducting clinical trials. Looking into the data, it was found private institutes were preferred compared with government institutes and increasing number of trials were also conducted in polyclinics. Trends toward allocating of private institute though increased by 2011 but by 2012, both government and private institutes were equally allocated for clinical trials but decrease in registration of trials is noticed by the 2012. Proper coordination and timely completion of trial should be aimed at properly trained, qualified, and experienced staff (GCP trained) with standard laboratories and regular monitoring.

**Conclusion:** Present study showed the importance and differences of site specific application of GCP objectives. The principle of GCP should be followed regardless of site and then expect a good clinical outcome and training during the study.

**Disclosure of Interest:** None declared.

## OC022—INTERCHANGEABILITY OF GABAPENTIN GENERIC FORMULATIONS IN THE NETHERLANDS: A COMPARATIVE BIOAVAILABILITY STUDY

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**Introduction:** This study (*in vivo*) was performed to investigate so-called “drift” with generic–generic drug substitution, namely whether a registered generic formulation is also bioequivalent to another generic formulation, fulfilling the 80% to 125% criterion.

**Patients (or Materials) and Methods:** This bioequivalence study was conducted at Maastricht University Medical Centre, and designed as a 800-mg tablet, single-dose, 4-treatment (Neurontin® and 3 registered generic gabapentin products), randomized, 4-way crossover trial in 24 healthy volunteers under fasting conditions.

**Results:** Six comparisons were performed among the 4 treatments to investigate the bioequivalence of different gabapentin formulations. In all comparisons, the 90% CIs for the reference/test ratio of  $C_{max}$ ,  $AUC_t$ , and  $AUC_{inf}$  were within the routine 80.00% to 125.00% criterion. The safety and tolerability profiles were comparable.

**Conclusion:** In this comparative bioavailability study, all 3 generic formulations of gabapentin were found to be interchangeable with Neurontin® and were also shown to be bioequivalent to each other. These results indicate the absence of a “drifting” problem upon gabapentin generic–generic exchange. Our study results are in line with those obtained from a previously conducted simulation study with topiramate and gabapentin based on bioequivalence data present in the registration files of the Dutch Medicines Evaluation Board<sup>1</sup>. Compared with the simulation study for generic–generic interchange, the ratios in the currently reported comparative bioavailability study are comparable, albeit with narrower 90% CIs for  $C_{max}$  and  $AUC_t$ .

**Disclosure of Interest:** None declared.

## Reference

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## OC023—DO TREATMENT QUALITY INDICATORS PREDICT CARDIOVASCULAR OUTCOMES IN PATIENTS WITH DIABETES?

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**Introduction:** Landmark clinical trials have led to optimal treatment recommendations for patients with diabetes. However, whether optimal treatment is actually delivered in practice is more important than the efficacy of the drugs tested in trials. To this end, treatment quality indicators have been developed and tested against intermediate outcomes of cardiovascular complications. No studies have tested whether these treatment quality indicators also predict hard patient outcomes.

**Patients (or Materials) and Methods:** Data were collected from 10,058 patients with diabetes in the Groningen Initiative to Analyze Type 2 Treatment (GIANTT) database and Dutch Hospital Data register. Included quality indicators measured glucose, lipid, blood pressure, and albuminuria-lowering treatment status and treatment intensification when indicated. Hard patient outcome was the composite of cardiovascular events and all-cause death. Associations